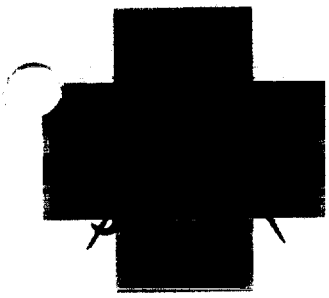

June 1, 1999

Office of Device Evaluation
Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Re: Reclassification Petition – Constrained Metal/Polymer Hip Prosthesis, 21CFR888.3310

Dear Sir/Madam:

The attached document (one volume, two copies submitted and additional copies will be provided upon request) is a Petition for Reclassification of Constrained Metal/Polymer Hip Joint Prostheses, 21CFR888.3310, and devices found substantially equivalent to them, from Class III to Class II.

The petition is being submitted under Section 515(i) (21 USC 360e (I)), with specific reference to FDA's 515(I) Order of August 14, 1995, which requires the submission of safety and effectiveness information on certain Class III devices, among which are Constrained Metal/Polymer Hip Prostheses. Please note that the information presented in the submission is organized in accordance with that Order rather than with the formal reclassification procedure of 21 CFR 860.123.

Your prompt attention to this submission will be very much appreciated as we anticipate the Orthopedic Device Panel will vote on this petition at the next panel meeting in July.

Sincerely,

Orthopedic Surgical Manufacturers Association

Tom Craig
President

99P-1864

ORTHOPEDIC SURGICAL MANUFACTURERS ASSOCIATION
An Association of Manufacturers Devoted to the Interest of the Surgical Patient
1962 Deep Valley Cove
Germantown, TN 38138 • Phone/Fax: 901-754-8097

CCP1

April 13, 1999 DRAFT

PETITION FOR RECLASSIFICATION

FOR

CONSTRAINED METAL / POLYMER HIP PROSTHESES

SUBMITTED BY:

THE ORTHOPEDIC SURGICAL MANUFACTURERS ASSOCIATION

DATE:_____

Constrained Hip Reclassification Petition

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Applicability of FR FDA 12/31/98 F 63 72171 - Financial Disclosure by Clinical Investigators

Based upon review of the Agency's Final rule; action on petition for reconsideration, we believe the financial disclosure by clinical investigators is not applicable to this submission for the following reasons.

The clinical data presented in this submission was collected retrospectively from commercially marketed devices cleared under 510(k) premarket notifications, and not as part of a covered clinical study. The surgeons who implanted these devices were not part of a clinical trial for the subject device. Moreover, the clinical data involving the S-ROM and the Omnifit were from peer-reviewed published literature.

In the above-referenced FR notice, the FDA amended the definition of clinical investigator in Sec. 54.2(d) *"....to clarify that it is intended to include only listed or identified investigators or sub-investigators who are directly involved in the treatment or evaluation of research subjects."*

The clinical data was generated by the treatment of clinical patients during the course of the surgeons' clinical practice, and were not considered to be research subjects. All surgeries and follow-up evaluations were performed prior to the compliance date of the final rule, February 2, 1999.

Conclusion.

The financial disclosure rule is not applicable to this submission due to the retrospective manner in which the clinical data on a previously marketed device was collected.

1. All cases and follow-up evaluations were completed prior to February 2, 1999.
2. The subjects were patients treated during the physicians' normal course of practice, and were not research subjects.
3. The retrospective collection of clinical data involving a commercially marketed device does not meet the definition of a covered clinical trial.

COMPLETED CLASSIFICATION QUESTIONAIRE
Medical Device Classification System

Petition Sponsors: Orthopedic Surgical Manufacturers Association
Date: April 13, 1999
Device: Hip Prosthesis, Metal / Polymer, Constrained, Cemented or Uncemented

Use Categories: ____Diagnostic ____Monitoring ___Prosthetic
_X__ Surgical ____Therapeutic ___Other

Regulatory Level: I. General Controls
II. Special Controls __X_
III. Pre-Market Approval
Specific Device Problems ___Yes __X_ No

Classification System	YES	NO	Do Not Know	Regulatory Level	Question Scheme
1. Custom Made		X			
2. Custom Made: Standard?	N/A	N/A			
3. Life Sustaining?		X			
4. Potentially Hazardous to Life, Good Health?		X			
5. (a) Can Standards be Developed Now; and	X				
(b) Would Standard be Adequate?	X				
6. Marketed in the United States?	X				
7. Remote from Body?		X			
8. Powered?		X			
9. Failure of Power: Hazardous to Patient?	N/A	N/A			
10. Introduce Energy Into Body?	N/A	N/A			
11. Acceptable Energy Levels?	N/A	N/A			
12. Safe Energy Levels if Malfunction?	N/A	N/A			
13. Material Regarded as Safe Without Standard?	X				
14. Prescriptions Needed? Limitation, Hazards, Difficulties, Problems		X			
15. Labeling Instructions Or Precautions of Measurement Function?	N/A	N/A			

16.	Performance Standards?	X
17.	Special Safety Systems Considerations?	X
18.	Potentially Hazardous to Fetus and/or Gonads?	X